K040326

FEB 2 5 2004

510(k) SUMMARY SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories
540 Alder Dr.
Milpitas, CA 95035

Contact: Joy M. Sacmar
Tel: (408) 468-3053
Fax: (408) 468-3050

B. Device Trade Name: AutoQUANT® Plus

Common Name: Gamma Camera Systems
Classification Name: Emission Computed Tomography System
Device Class: 21 CFR 892.1200, Class II
Product Code: 90 KPS

C. Date prepared: January 12, 2004

D. Predicate Device (s):

Manufacturer	Product Name	510(k) No.
ADAC Laboratories	AutoQUANT®	K980715
ADAC Laboratories	Quantitative Blood Pool SPECT (QBS)	K022428

E. Intended Use:

AutoQUANT® Plus applications are intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. AutoQUANT® Plus may be used in multiple settings including the hospital, clinic, doctors office, or remotely via dial up. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

F. Device Description:

AutoQUANT® Plus is a suite of applications for the processing and review of Cardiac SPECT and blood pool SPECT datasets. AutoQUANT® Plus is composed of the following applications: AutoQUANT® (K980715) [AutoQUANT integrates 2 functionalities, Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) into a single application for LV (Left Ventricle) extraction and analysis], Quantitative Blood Pool SPECT (QBS) (K022428), and optionally QARG (for reporting purposes). Previously, the marketing clearance for QBS (K022428) was separate and is now being combined with the AutoQUANT Plus 510(k) being submitted.

AutoQUANT® is a software application designed to enable an automated, comprehensive review and quantification of Cardiac SPECT data. AutoQUANT® integrates 2 functionalities, Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) into a single application for LV (Left Ventricle) extraction and analysis. AutoQUANT® provides a tool to review and quantify all types of Cardiac SPECT data sets (perfusion and/or gated) to determine the location, orientation, and anatomical extent of the left ventricle of the heart, to construct 3D contour maps of the heart, and to calculate the heart volume (for the left ventricular wall), the lung/heart ratio, and transient ischemic dilation (TID). Physicians use this information to assess the anatomical and physiological functionality of the heart and analyze the presence of myocardial defects through comprehensive imaging modalities.

Also included in AutoQUANT Plus is Quantitative Blood Pool SPECT (QBS). QBS is an interactive standalone software application for the automatic segmentation and quantification of gated short axis blood pool (red blood cells, RBC) SPECT. The application can be used for automatic generation of left and right ventricular endocardial surfaces and valve planes from three-dimensional (3D) gated short axis blood pool images; automatic calculation of left and right ventricular volumes and ejection fractions; calculation and display of polar maps representing wall motion and parametric values (FFH amplitude and phase); two-dimensional (2D) image display using standard American College of Cardiology (ACC) cardiac SPECT conventions; and 3D image display. It also provides the following functionalities: ability to combine isosurfaces extracted from the data with the calculated endocardial surfaces in various ways (endocardial borders displayed as wireframes, shaded surfaces, both, or parametric); ability to map parametric values (First Fourier Harmonic (FFH) amplitude and phase) on the surfaces; ability to display parametric images (FFH amplitude and phase) for gated planar, gated raw projections and gated short axis images; ability to display cine loops of the original images; ability to generate count-based quantitative values using the automatically- and semi automatically-computed surfaces as ROIs and user-selectable thresholds; ability to generate and display phase histograms for FFH phase images and to display the mean and standard deviation of the peaks corresponding to atrial and ventricular voxels. After ventricular segmentation, a phase histogram for each ventricle is also computed and displayed; and ability to display normalized images for all gated images (i.e., images that do not exhibit count drop-off caused by arrhythmia). In addition, QBS supports manual identification of the left-ventricular (LV) region, to separate it from the right ventricle (RV) in cases where the automatic algorithm fails or returns unsatisfactory results; ability to generate filling rates from interpolated time-volume curves; and the ability to rotate, zoom, and cine surfaces.

In addition, an automatic report generation (ARG) feature has been added to AutoQUANT® Plus. This option in AutoQUANT produces consistent PDF (or text) reports based on a series of form elements within AutoQUANT . The tool consists of an additional window within AutoQUANT and does not alter any quantitative values. This is designed to reduce transcription errors and automate workflow. A separate QARG application allows searching and management of the ARG database, which requires all data to be manually entered. There are no algorithmic functions within the ARG/QARG feature.

G. Technological Comparison:

The AutoQUANT®Plus and predicate AutoQUANT®/QBS Software Applications have similar indications for use and utilize the same type of data sets for analysis and calculation of data.

H. Conclusion:

AutoQUANT® Plus is substantially equivalent to the following predicate devices, AutoQUANT® (K980715) and QBS (K022428) based on similar intended use and technological comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2004

ADAC Laboratories
% Ms. Denise Leung Klinker
Reviewer
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K040326
Trade/Device Name: AutoQUANT® Plus
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: January 21, 2004
Received: February 10, 2004

Dear Ms. Klinker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K040326

DEVICE NAME: AutoQUANT® Plus

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

AutoQUANT® Plus applications are intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. AutoQUANT® Plus may be used in multiple settings including the hospital, clinic, doctors office, or remotely via dial up. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____
(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040326